



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,534	02/20/2004	David Alan Mead	MICRO-08797	7480

7590 04/18/2006

MEDLEN & CARROLL, LLP
Suite 350
101 Howard Street
San Francisco, CA 94105

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/783,534	Applicant(s) MEAD ET AL.	
	Examiner Daniel M. Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 13 February 2006 in response to the Non-Final Office Action mailed 9 August 2005. Claims 29-41 were considered in the 9 August Office Action. Claims 29, 31, 32, 35 and 37 were amended in the 13 February Paper. Claims 29-41 are pending and under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

Rejection of claims 29-41 under 35 U.S.C. 112, second paragraph, as being for the reason set forth in the 9 August Office Action at pages 3-4 is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 102

Claims 29-34 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Chen *et al.* (1987) *Gene* 55:179-187 (made of record in the IDS filed 16 August 2004) as evidenced by Kobayashi *et al.* (1986) *J. Bacteriol.* 166:728-732 and Altieri *et al.* (1986) *J. Bacteriol.* 168:648-654 for the reasons set forth in the 9 August Office Action at pages 4-6 and herein below in the response to Applicant arguments.

Art Unit: 1636

Response to Arguments

In response to the *prima facie* rejection of record, Applicant has amended claim 29 such that the selectable marker region, origin of replication and first transcriptional terminator are located between the first and second ends. Applicant contends that the art does not anticipate the amended claims because the pJDC9 plasmid is not arranged as specified in claim 29. In particular, Applicant contends that pJDC9 does not have a second transcriptional terminator between the toxic gene sequence and the first end of the nucleic acid sequence and a third transcriptional terminator between the toxic gene sequence and the second end of the nucleic acid sequence.

This argument has been fully considered but is not deemed persuasive. Although the amended claim specifies that certain elements must be located between the first and second ends, the claim does not exclude the toxic gene sequence of (a) from the region bounded by the first and second ends. Therefore, the following configuration is within the scope of the claimed vector:

First end—2nd terminator—selectable marker—1st terminator—origin of replication—
toxic gene—3rd terminator—second end.

According to this configuration, the first transcriptional terminator is downstream of the selectable marker, the second transcriptional terminator is between the toxic gene and the first end of the nucleic acid sequence and the third transcriptional terminator is between the toxic gene and the second end of the nucleic acid sequence as required by the claim. Figure 1 of Chen *et al.* shows that defining the first and second ends of the pJDC9 vector as the opposite ends of

Art Unit: 1636

the PvuII cleavage site at base 601 results in the above configuration. Therefore, the pJDC9 vector of Chen *et al.* is still within the scope of the claims.

It is additionally noted that, because the vector is circular, any given point in the vector can be construed as between any other two points in the vector. For example, considering pJDC9 in the clockwise direction: starting from the ClaI site, the PvuII 5080 site is between the ClaI 3575 and the PvuII 5450 sites; starting from the PvuII 5080 site, the PvuII 5450 site is between the PvuII 5080 and ClaI 3575 sites; and starting from the PvuII 5450 site, the ClaI 3575 site is between the PvuII 5450 and Pvu II 5080 sites. Thus, all permutations are possible in view of the fact that the claimed invention is a circular molecule.

With regard to claim 32, which has been amended to recite that the selectable marker region comprises first and second selectable marker genes, the claim is also still within the scope of Chen *et al.* as evidenced by Kobayashi *et al.* In the section bridging the left and right columns on page 157, Chen *et al.* describes the construction of pJDC9 and that an erythromycin antibiotic resistance gene (*i.e.*, Er^R) was used to select for transformants. Thus, in addition to the LacZ marker gene, the plasmid also comprises a second, Er^R marker gene.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §102(b).

Claim Rejections - 35 USC § 103

Claims 35-41 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (*supra*) as evidenced by Kobayashi *et al.* (*supra*) and Altieri *et al.* (*supra*) in view of "Directional Cloning" in Molecular Cloning, a laboratory manual (Maniatis *et al.*, Eds.) Cold

Art Unit: 1636

Spring Harbor Laboratory, 1982, pp. 13 (hereinafter, Maniatis *et al.*) for the reasons set forth in the 9 August Office Action commencing at page 7 and herein below in the response to Applicant arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant contends that the claim amendments render the claims patentably distinct from the teachings of the art. The basis for this contention is the same as described herein above regarding the claim rejections under 35 USC §102(b). The argument has been fully considered but is not deemed persuasive because, as described herein above, the pJDC9 vector of Chen *et al.* is within the scope of the claimed invention and for the reasons stated in the previous Office Action, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cloning method described in Chen *et al.* to include digestion of a second restriction enzyme recognition site present in the multiple cloning site of pJDC9 according to the limitations of the instant claims.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §103(a) as obvious over the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1636

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636


DANIEL M. SULLIVAN
PATENT EXAMINER